

**MEMORANDUM DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH**

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**SUBJECT: Drug: Acetaminophen Utilization
 Topic: Hepatotoxicity
 PID#: D010092**

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I. EXECUTIVE SUMMARY

This report is prepared in response to a request from the Division of Over-the Counter Drugs to study the utilization of acetaminophen (APAP)-containing products in available national databases.

- In 2000 there were about 24 billion units of APAP sold; OTC products account for 70% of these units and the remaining 30% of units are prescription products.
- APAP containing products are one of the most frequently mentioned medications in ambulatory care settings including out-patient hospital clinics, emergency departments and physicians' offices. About 42% of APAP products used in these settings were non-prescription medications.

II. INTRODUCTION

The utilization of APAP-containing products is addressed by analyzing (1) IMS HEALTH, Provider Perspective and Retail Perspective AuditsTM, extracted September 2001, (2) the National Ambulatory Medical Care Survey, and (3) both components of the National Hospital Ambulatory Medical Care Survey (NHAMCS): Emergency departments (ED) and Outpatient Departments (OPD).

IMS HEALTH Provider Perspective and Retail Perspective are continuing monthly reports measuring, in dollars and units, pharmaceutical products purchased by providers of health care, such as hospitals, clinics and long term care facilities (Provider Perspective) and by independent pharmacies, mail services, chain drugstores, proprietary stores, mass merchandisers, and foodstores with pharmacies (Retail Perspective) in the entire United States.

The National Ambulatory Medical Care Survey (NAMCS) is a national survey that estimates the use of ambulatory medical care services in the United States. Findings are based on a multi-stage sampling design of visits to nonfederally employed office-based physicians who are primarily engaged in direct patient care. Physicians in the specialties of anesthesiology, pathology, and radiology are excluded from the survey. Data are obtained on patients' symptoms, physicians' diagnoses, and medications ordered or provided. The survey also provides statistics on the demographic characteristics of patients and services provided, including information on diagnostic procedures, patient management, planned future treatment, and drug information.

The National Hospital Ambulatory Medical Care Survey (NHAMCS) is designed to collect data on the utilization and provision of ambulatory care services in hospital emergency (ED) and outpatient departments (OPD). Findings are based on a national sample of visits to the emergency departments and outpatient departments of noninstitutional general and short-stay hospitals, exclusive of Federal, military, and Veterans Administration hospitals, located in the 50 States and the District of Columbia. The survey is a multistage probability design with samples of geographically defined areas, hospitals within these areas, clinics within hospitals, and patient visits within clinics. Annual data collection began in 1992.

III. RESULTS

IMS HEALTH Provider Perspective and Retail Perspective provides a national estimate of total units (number of individual tablets, capsules, etc.) of APAP products purchased in the United States. In the year 2000 there were about 24 billion units of APAP sold; OTC products accounted for 70% of these units and the remaining 30% of units were prescription products. OTC products were purchased equally as either a single or combination entity (51% single vs. 49% combination entity), whereas, the prescription products were almost exclusively combination entities (0.02% single vs. 99.98% combination).

Based on other published reports, APAP-containing products are one of the most frequently medications in ambulatory care settings including out-patient clinics, emergency departments and physicians' offices (1-3). In 1999, there were 22,290,000 (in NHAMCS, emergency departments), 5,831,000 (in NHAMCS, outpatient hospital departments), and 36,343,000 (in NAMCS, office-based visits) mentions of APAP containing products (1-3). Table 1 displays the distribution of OTC products and percent age and sex by type of ambulatory setting for visits in which APAP-containing products were mentioned. As this table shows, a total of 64,454,000 APAP containing products were mentioned in a total of 62,390,000 visits made to the ambulatory care system. About 42% of these products were non-prescription medications. One reason why this estimate is much smaller than the IMS HEALTH estimate is that both NHAMCS and NAMCS surveys collect only the medications which are mentioned or prescribed by

physicians and not those medications used without physician direction. The second reason is that IMS HEALTH Provider Perspective and Retail Perspective counts the tablets purchased by retail outlets and health care providers, not the number of prescriptions dispensed or advice made by physicians.

As this table shows, OTC products were mentioned more frequently on visits made to outpatient hospital clinics than any other type of setting (i.e. 58.0% in OPD vs. 46.0% in ED and 36.3% in office-based visits).

Among all visits (ED, OPD, office-based visits) with mentions of APAP-containing products, the distribution of age groups (<6, 6-19, 20-64, and >64 years of age is about 12.6, 10.5, 59.0, and 17.9 percent respectively). APAP products for very young children (younger than 6 years of age) are more likely to be over-the-counter than prescription (data not shown).

IV. SUMMARY

Acetaminophen is a highly utilized drug, particularly OTC. The drug is used by both men and women and all age groups. Any serious adverse events associated with this drug, even rare ones, could be a public health concern given the utilization patterns.

Table1. The percent distribution of selected variables for visits in which APAP-containing products were mentioned by type of setting, United States, 1999

Variables	Total (N=62,390,000) Visits	NHAMCS Emergency Department (N=21,430,000) Visits	NHAMCS Outpatient, Hospital Department (N=5,679,000) Visits	NAMCS Office-base Physicians (N=35,280,000) Visits
<i>Products</i>				
Over-the-counter	41.6	46.0	58.0	36.3
Prescription	59.7	56.4	44.4	64.1
<i>Age distribution</i>				
Less than 6 years	12.6	16.7	21.7	8.7
6-19 years	10.5	14.3	12.1	8.0
20-64 years	59.0	58.4	51.7	60.5
65+ years	17.9	10.6	14.6	22.9
<i>Sex</i>				
Female	55.0	52.1	56.8	56.4
Male	45.0	47.9	43.2	43.6

References:

1. Cherry D.K., Burt C, and Woodwell D. (1999): National Ambulatory Medical Care Survey; 1999 summary. Advance data from Vital and Health Statistics. No. 322. Hyattsville, Maryland.
2. Ly N, McCaig L., and Burt C. (1999): National Hospital Ambulatory Medical Care Survey; 1999 Outpatient Department summary. Advance data from Vital and Health Statistics. No. 321. Hyattsville, Maryland
3. McCaig L. and Burt C. (1999): National Hospital Ambulatory Medical Care Survey; 1999 Emergency Department summary. Advance data from Vital and Health Statistics. No. 320. Hyattsville, Maryland.